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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,790	01/23/2002	Mario N. Lioubin	EX02-004C	1603

23500 7590 08/01/2003

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/01/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,790

Applicant(s)

LIUBIN ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 13-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4&5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group II in Paper No. 9 is acknowledged.
2. Claims 1-51 are pending, claims 1-7 and 13-51 are withdrawn from further consideration as being drawn to non-elected subject matter. Applicant is reminded to cancel claims drawn to inventions non-elected.
3. Therefore, claims 8-12 are examined on the record.

Information Disclosure Statement

4. The Information Disclosure Statements filed 5/17/02 & 3/25/02 (paper no. 4 & 5) are acknowledged and considered. A signed copy of the IDS is attached hereto.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See pages, 8,44 for example.

Claim Rejections - 35 USC § 112, 2nd paragraph

6. Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. With regard to claims 8, 11, 12 and dependents thereof, in the recitation of the term "RRP", it is unclear as the metes and bounds of the term. Barg S *et al* (Neuron. 2002 Jan 17;33(2):287-99) disclose that RRP is "a readily releasable pool". Savino TM

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et al (J Cell Sci. 1999 Jun;112 (Pt 12):1889-900) describe RRP1-RRP6 as ribosomal RNA processing proteins. Because the term used in the instant invention can fall within the scope of "RRP" used by Barg S *et al* or Savino *et al*, the term is considered indefinite. This term is considered a laboratory term of which many possible meanings can be derived. Applicant is advised to amend the claim to recite the full name of the instantly claimed protein.

Claim Rejections - 35 USC § 112, 1st paragraph

8. Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an RRP1-2, 4-8 and mouse RRP1 (mRRP1) having SEQ ID Nos: 36-44, and 46 does not reasonably provide enablement for all RRP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims of the instant invention are drawn to a method of screening for an agent that modulates that the interaction of an RRP polypeptide with an RRP binding target.

The specification specifically teaches the characterization of 8 different RRP polypeptides by sequence identification numbers (RRP1-2, 4-8, and mRRP1). However, the specification has not taught the scope of the proteins encompassed by the term RRP. Szakmary *et al* (PNAS USA 1996; 93:1607-1612) teach an RRP1 molecule that is involved in the repair of oxidative DNA damage. Savino *et al* teach another RRP1 protein that is involved in pre-rRNA processing from 27S to 25S and

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5.8S. Therefore, given the fact that there are multiple forms of RRP proteins that seem to be involved in distinctly different functions, have different protein structures, the specification has not enabled methods of screening for any and all agents that may or may not modulate all forms of RRP. Because these RRPs seem to have different functionalities, the resulting endpoints disclosed by the method cannot be properly assessed to all forms of RRP. The disclosure of the instant specification has only enabled the assaying of RRPs and their involvement in the EGFR signal transduction pathway. As such one of skill in the art would be forced into undue experimentation to determine the distinct endpoints for agents that would modulate other RRPs encompassed by the claims of the instant invention.

Therefore, considering large quantity of experimentation needed, the state of the art, and the breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
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July 25, 2003

